



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

JUL 31 1997

#37

Thomas D. Hoffman  
SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1-1990)  
2000 GALLOPING HILL ROAD  
KENILWORTH NJ, 07033-0530

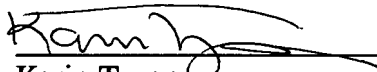
Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,634,697

Dear Mr. Hoffman:

This is in response to the request for reconsideration, filed May 27, 1997, requesting reconsideration of the final determination in the above-identified patent, which required an election of a single patent and a single regulatory review period for patent term extension under 35 U.S.C. § 156, is acknowledged. Applicant's arguments have been carefully considered and are persuasive.

Accordingly, a certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,634,697 for a period of five years from the original expiration date of the patent, October 1, 2004, until October 1, 2009, based upon the regulatory review period of CEDAX® (ceftibuten dihydrate - oral suspension).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

  
Karin Tyson  
Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: CEDAX® (ceftibuten dihydrate  
- oral suspension)  
FDA Docket No.: 96E-0102

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE EXTENDING PATENT TERM  
UNDER 35 U.S.C. § 156

PATENT NO. : 4,634,697  
ISSUED : January 6, 1987  
INVENTOR(S) : Yoshio Hamashima  
PATENT OWNER : Shionogi & Co., Ltd.

This is to certify that there has been presented to the

COMMISSIONER OF PATENTS AND TRADEMARKS

an application under 35 U.S.C. § 156 for an extension of the patent term. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

Five years

from October 1, 2004, the original expiration date of the patent, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the Patent and Trademark Office to be affixed this 31st day of July 1997.

*Bruce A. Lehman*

Bruce A. Lehman

Assistant Secretary of Commerce and

Commissioner of Patents and Trademarks